No. 05-35264

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE;
Animal and Plant Health Inspection Service; et al.,
Defendants-Appellants.



On Appeal from the United States District Court
for the District of Montana

# REPLY BRIEF FOR APPELLANTS

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## INTRODUCTION AND SUMMARY OF ARGUMENT

The challenged rulemaking addressed one ultimate question: whether cattle and other ruminants and meat from such ruminants may safely be imported from Canada despite the existence of isolated cases of BSE in that country. The Secretary of Agriculture's conclusion that cattle under 30 months of age and certain beef products may safely be imported for purposes of immediate slaughter is set out in a detailed decision that rests on a voluminous record. It is not suggested that the Secretary's decision was based on impermissible factors or that the broad grant of statutory authority vested in the Secretary compelled a different conclusion. R-CALF's brief, like the opinion it defends, provides no basis for setting aside the Secretary's scientific assessments and predictive judgments.

The rulemaking is the first to consider the risks posed by

BSE in a comprehensive fashion. Consistent with international standards developed with the active participation of the United States, the Secretary recognized that diagnosis of BSE in one or more cows may not require a total ban on cattle importation from that region. Instead, the threat posed by isolated instances of BSE should be analyzed with respect to a nation's safety regime for controlling the disease.

In applying that framework to Canada, the Secretary explained that that nation's current regulatory framework parallels that of the United States. Both the United States and Canada implemented a virtually identical feed ban on the same date in 1997. Because a feed ban is crucial to precluding the dissemination of BSE, the risk of cases of BSE in cattle born before or near the time the feed ban was instituted cannot entirely be discounted, as evidenced by the isolated cases diagnosed in Alberta. No reason exists, however, to believe that these instances of BSE indicate a widespread problem even in older cattle or that they suggest any risk with regard to much younger cattle. Accordingly, the rule permits importation only of cattle under 30 months of age for immediate slaughter, an age far younger than <u>any</u> case of BSE diagnosed in Canada.

The Secretary further explained that an array of regulatory measures would ensure against dissemination of BSE even if it were introduced. That was the finding of the authoritative Harvard-Tuskegee study discussed in the rulemaking, which assumed

a worst-case scenario but concluded that even under those circumstances it would be extremely unlikely for BSE to infect the cattle population or result in human exposure.

Plaintiff identifies no legitimate basis for setting aside the Secretary's determination. R-CALF does not suggest that any Canadian cow under 30 months of age has ever been diagnosed with BSE. Rhetoric aside, it cannot explain why the Secretary should have believed that the strictly limited imports permitted under the rule would pose a risk of introducing BSE. Nor can it point to any unsoundness in the Secretary's conclusion that the risks of dissemination would be minimal even assuming the introduction of BSE.

Plaintiff's argument is not so much that the Secretary's determination was unreasonable but that the district court's assessment should be allowed to stand because it is not "clearly erroneous." This gets matters precisely backwards. Under controlling law, a court may not substitute its judgment for that of the agency unless the agency's decision is arbitrary and capricious. A court may not issue an injunction, preliminary or otherwise, based on legal error, and this Court owes no deference to the district court's disagreements with the Secretary's conclusions.

In any event, both the premises and conclusions of the court's opinion <u>are</u> clearly erroneous. The court fundamentally erred in holding the regulation invalid because the Secretary's

assessment of risk was not expressed in "quantitative" form. And, as we showed in our opening brief, the court's characterization of the regulation and the underlying record is simply inaccurate.

R-CALF's invocation of the balance of harms does not alter the analysis. The only cattle importable under the rule are under 30 months of age for purposes of slaughter. There has never been a confirmed case of BSE in Canadian cows of this age, and R-CALF offers no reason whatsoever to believe this is mere coincidence. Nor has any person ever contracted vCJD from consuming Canadian beef regardless of the age of the cattle. Indeed, in another brief filed by R-CALF with this Court in this litigation, plaintiff stresses that it has "never argued that there was a great risk to human health from resumed imports of cattle and beef from Canada." R-CALF Br. in No. 05-35214, at 44.[1]

The harm on which R-CALF focuses in discussing the balance of harms is not risk to health but its predictions of the economic impact created by the discovery of a BSE-infected cow in the United States. At bottom, therefore, plaintiff asserts that

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[1] The National Meat Association (NMA), a putative intervenor in the district court, has filed its own appeal of the district court's decision, challenging both the denial of its motion to intervene as well as the preliminary injunction itself. This Court has ordered that to the extent practicable, NMA's appeal (No. 05-35214) and this one should be placed before the same merits panel for disposition.

the district court was entitled to give short shrift to the Secretary's safety judgment in order to avoid possible economic harm to R-CALF. This uninspiring argument requires the Court to accept R-CALF's speculations while ignoring the real and significant adverse impact that the injunction imposes on other parties, as well as on our trading partners, on an ongoing basis.

As the many filings of amici curiae indicate, the significance of the court's injunction cannot be overstated. R-CALF has for months been able to halt imports that the Secretary has properly determined may safely enter the United States. We ask that the Court act at the earliest possible time to vacate an injunction premised on legal error that cannot be justified on the basis of safety.

## ARGUMENT

### I. R-CALF HAS NO LIKELIHOOD OF SUCCESS ON THE MERITS.

#### A. The Controlling Question In Evaluating The Merits Is Whether The Secretary's Determination Was Reasonable, Not Whether The District Court's Conclusions Were "Clearly Erroneous."

As R-CALF emphasizes, this Court reviews the grant of a preliminary injunction for abuse of discretion. But "[t]he district court's interpretation of the underlying legal principles . . . is subject to de novo review and a district court abuses its discretion when it makes an error of law." Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d

914, 918 (9th Cir. 2003) (en banc); see USDA Br. 19.

R-CALF mistakenly believes that the standards governing issuance of a preliminary injunction incorporate a tolerance for legal error. When a plaintiff can establish that an injunction is necessary to prevent irreparable harm, it need not demonstrate to a certainty that it will prevail on the merits. But that does not suggest that a district court may issue an injunction based on legal error or that a court of appeals will overlook the error when it is identified.

R-CALF likewise errs when it attempts to convert the district court's disagreements with the Secretary into findings of fact subject to a "clearly erroneous" standard of review. R-CALF states in a footnote, without explanation or authority, that "[t]he District Court's conclusions were factual ones," R-CALF Br. at 8 n.3, and asserts that this Court may not exercise "de novo review of those judgments," id. at 8. That is at odds with bedrock principles of administrative law. "Generally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." James Madison Ltd. v. Ludwig, 82 F.3d 1085, 1096 (D.C. Cir. 1996), cert. denied, 519 U.S. 1077 (1997). Accordingly, when a district court reviews agency action under the APA, "the entire case on review is a question of law." PPG Industries, Inc. v. United States, 52 F.3d 363, 365 (D.C. Cir.

1995).

Under settled law, an agency's judgment should be sustained unless arbitrary and capricious, and the district court commits legal error if it impermissibly substitutes its judgment for that of the agency. That is particularly the case when a statute, by its terms, vests broad discretion in the agency and no claim exists that the Secretary violated statutory standards. See 7 U.S.C. § 8303(a)(1) (authorizing Secretary to restrict imports "if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock"). Deference is also particularly appropriate when a court reviews a predictive scientific judgment within the agency's expertise. See USDA Br. at 21. It is the district court's judgment, not the Secretary's decision, that is reviewed de novo.

### B. R-CALF Identifies No Respect In Which The Rule Is Arbitrary And Capricious Or Fails To Address Relevant Factors.

#### 1. The Secretary Was Not Required To Adopt A "Quantitative" Risk Standard.

Although R-CALF portrays the regulation as the "abandonment of a key protection against BSE infection in the United States," R-CALF Br. at 16, the present rulemaking was the first occasion on which the agency addressed the efficacy of mitigation procedures and the risks posed when effective mitigation procedures are in place. As explained in our opening brief, BSE

was first diagnosed in 1986. In previous regulatory actions, USDA simply banned all importations from countries with any reported cases of BSE, a policy that reflected the dearth of scientific knowledge and the absence of regulatory experience. See USDA Br. 7.

Since that time, the understanding of BSE has grown enormously. The international body charged with developing standards and recommendations with respect to animal health, with the active participation of the United States, has recognized that discovery of an instance of BSE may not be an appropriate basis for banning all ruminant exports. See 70 Fed. Reg. at 463 (citing guidelines developed by the Office International des Epizooties (OIE)).

Building on the work of OIE and the international scientific community, the USDA rule did not relax safety standards; for the first time, the agency, based on a comprehensive record, was able to determine what the appropriate standards should be. In particular, it is now understood that BSE is transmitted through animal feed containing protein from other infected animals. Feed bans have thus proven to be crucial and efficacious. 70 Fed. Reg. at 463. Because BSE has a long period of incubation, it is therefore important that a feed ban have been in place for several years and that it be rigorously policed.

The Secretary explained that evaluations of the safety of imports from Canada and other regions would turn on three crucial

inquiries: (1) Does the nation have in place risk mitigation measures, including a feed ban, adequate to prevent widespread exposure or establishment of the disease? (2) If BSE has been detected, has the nation conducted an epidemiological investigation sufficient to confirm that the measures it has in place are sufficient to prevent the further introduction or spread of BSE? (3) If BSE has been detected, has the nation taken additional ongoing risk mitigation measures? 70 Fed. Reg. at 463.

The district court believed that the regulation was presumptively invalid because it failed to adopt a "quantitative" standard of acceptable risk, and R-CALF urges this Court to accept that central premise. R-CALF argues that USDA was required to quantify a specific numerical threshold for an "acceptable number" of BSE cases in Canada, see R-CALF Br. 21, and argues that the district court correctly concluded that the absence of quantified conclusions renders the rule "arbitrary and capricious and unsupported by the record," ibid. (citing ER 116-17).

Plaintiff is very wide of the mark. Conclusions need not be expressed in numerical form to be scientifically valid, and many risk-predictions cannot legitimately be expressed in that form at all. The question, instead, is whether the Secretary considered relevant scientific evidence and articulated a reasonable conclusion. That is clear as a matter of logic and is amply

supported by the authority discussed in our opening brief, see USDA Br. 32-34.

Ignoring those decisions, R-CALF relies (Br. 22) on Ober v. Whitman, 243 F.3d 1190 (9th Cir. 2001), in which this Court upheld EPA's Clear Air Act plan that exempted from control certain "de minimis" sources of pollution. The EPA was required to "'describ[e] the standard under which [it] . . . arrived at this conclusion,'" and to support the conclusion with a "plausible explanation," including citation to "information to explain" the exemption, id. at 1195 (citation omitted). Although the agency provided such an explanation, the plaintiff insisted that EPA must "describ[e] the precise public health effect of each of these small amounts" of de minimis pollution. Id. at 1197. This Court rejected the plaintiff's demand, holding that the EPA's Clean Air Act mandate was to "protect the public health," ibid., which the EPA satisfied by providing a reasonable public-health explanation for its conclusion. "[W]e do not believe," the Court concluded, "that the EPA was required to analyze more specifically the effect of the de minimis sources on the public health." Ibid.

It is unclear how plaintiff believes this decision advances its argument. USDA provided a detailed description of the kinds of safeguards it deemed necessary and why those safeguards would be sufficient, and explained thoroughly why Canada's mitigation efforts satisfied that standard. As USDA explained, it "did not

specify numeric thresholds" for its minimal-risk criteria because "the most successful regulations must also be flexible enough to allow a country to consider individual circumstances among its trading partners, as well as changes in science, without undergoing constant revisions." 70 Fed. Reg. at 473. And the kind of "rigid criterion" sought by R-CALF "could result in trade with a region that may meet numeric criteria, but, nonetheless, present, in [USDA's] view, an undue risk of BSE introduction." Ibid. See also id. at 504 (noting that "[e]xperts in the field of risk analysis generally agree that different methods of risk assessment are appropriate in different circumstances," and that "OIE Guidelines . . . recognize both qualitative and quantitative risk assessment methods as valid").

**2. Plaintiff's Efforts To Discover Error In The Secretary's Assessment Of Canada's Safety Regime Are Unavailing.**

The basis for the Secretary's determination to permit importation of cattle under 30 months from Canada is set out in detail in the regulation and in our opening brief. The Secretary noted, in particular, that: (1) Since 1997, Canada has had in place a rigorous feed ban, and its inspections have verified a high level of compliance, see USDA Br. 3, 27, 36-39; (2) For seven years (as of the time of the rulemaking) Canada has conducted effective surveillance of, and testing for, BSE, which meet and exceed levels recommended by the OIE, see USDA Br. 11, 27-28; (3) In 1993, Canada traced and killed all cattle imported

from the U.K. or Ireland, see USDA Br. 27; and (4) Upon detection of BSE, Canada has responded rapidly with epidemiological investigations upon the detection of BSE, see USDA Br. 28.

The rule explicitly addressed the relation of identified cases of BSE to the effectiveness of Canada's regulatory measures and to any risk of introducing BSE into the United States. The Secretary recognized that BSE had been diagnosed in two cows born before the feed ban was instituted, and did not discount the possibility "that additional BSE-infected cattle may exist in Canada," although he found no evidence that these cases indicated a widespread incidence of BSE even among older cattle. 70 Fed. Reg. at 514. The Secretary stressed that the rule permitted importation of live cattle only under 30 months of age for slaughter. Ibid. Neither of the cows that had been diagnosed with BSE would have been importable under the rule because they both far exceeded the age limit.

R-CALF's scattershot attack on the Secretary's decision scores no hits.

**a. The Restriction On All Imports Of Live Cattle Over 30 Months of Age.**

R-CALF recognizes, as it must, that the isolated instances of BSE in Canadian cattle have all occurred in cows far older than 30 months and that none could therefore have been imported into the United States under the regulation. Plaintiff is thus hard-pressed to explain why the rule poses a risk of introducing

BSE into the United States.

Plaintiff argues, for example, that under "under the Final Rule as originally issued," meat products from Canadian cattle over 30 months of age could have been imported. The rule set out the reasons for the different treatment accorded to meat products and to live cattle, which could only be imported if under 30 months. 70 Fed. Reg. at 494. Nevertheless, after two cows were diagnosed with BSE in January 2005 in Alberta, the Secretary, in an abundance of caution, delayed the applicability of the portion of the rule that would have permitted the importation of certain Canadian beef products derived from cattle 30 months of age or older. 70 Fed. Reg. 12,112 (Mar. 11, 2005). The amended final rule with respect to beef products was not enjoined and is not the subject of this appeal. To the extent that plaintiff seizes on the amendment to cast doubt on the restriction on live cattle under 30 months of age, its argument is unclear.

Plaintiff seeks to cast doubt on the efficacy of the 30-month restriction by arguing that the incubation period for BSE in Canadian cattle is not really over seven years but 4.2 years. Therefore, in plaintiff's view, even younger Canadian cattle might be infected. See R-CALF Br. 34-36. That argument finds no support in any of the isolated incidents of BSE diagnosed in Canada and misunderstands the relevant science. As explained in our opening brief, USDA Br. at 26-27, 38-39, the incubation period varies directly with the amount of infected material

consumed. See 70 Fed. Reg. at 483 ("the larger the infectious dose received, the shorter the incubation period"); ER 319-321. While the mean incubation period in the U.K. was 4.2 years, see ER 77, "the same level of exposure is not likely to develop in Canada," and therefore "[t]he expected incubation period in Canada could be longer," ibid. See also Appellee's Supplemental Excerpts of Record (SER) 292-293 (USDA explaining the different incubation periods to the district court). Accordingly, it is not at all surprising that the four infected Canadian cows had a long incubation period.[2]

Relatedly, R-CALF argues the rule arbitrarily fails to address the possibility that BSE could be transferred through offspring of Canadian cattle. See R-CALF Br. 43. As explained in our opening brief, however, live cattle imported from Canada would be either immediately slaughtered or fed and then immediately slaughtered. See USDA Br. 40-41. The rule thus affords no opportunity to divert heifers for breeding or for

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[2] Similarly, R-CALF asserts that because four Canadian cows have been diagnosed as infected with BSE, because all four of those cows were born before or shortly after Canada imposed its feed ban in 1997, and because the incubation period for infected Canadian cows is over seven years long, there must be other infected Canadian cows born before or shortly after the feed ban was imposed. See R-CALF Br. 30, 36-37 n.16. Even assuming this is correct, R-CALF again disregards the fact that no such cattle could be imported under the final rule, because they would all be well over 30 months old. As noted above, that was true of the four infected cows, see supra at 12, and it would be true as well for any such cows imagined by R-CALF. ER 272; 70 Fed. Reg. at 548.

births from pregnant cows. Moreover, the risk of BSE maternal transmission "has not been proven and, if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic." 70 Fed. Reg. at 515.

**b. Efficacy Of The Canadian Feed Ban And BSE Testing Program.**

R-CALF does not indicate any significant respect in which the Canadian feed ban is not effective or is less strict than that in the United States, and its specific concerns are meritless. Plaintiff urges that "poultry litter and plate waste" should be kept out of cattle feed," R-CALF Br. 37-38, but Canada does precisely that. See 70 Fed. Reg. at 467 ("Canada prohibits the feeding of plate waste and poultry litter to ruminants."); id. at 491 (feed ban prohibits materials including "plate waste and poultry litter").

R-CALF points to the need to avoid "cross-contamination in feed mills," R-CALF Br. 38, but "Canadian Government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. Procedures to reduce the likelihood of cross-contamination are in place at all feed mills that handle both prohibited and nonprohibited feeds." 70 Fed. Reg. at 476.

R-CALF also argues that Canada's feed ban is ineffective because it does not ban blood in ruminant feed. See R-CALF Br. 37. But, as explained in our opening brief, the evidence on the

transmission of BSE through blood transfusions in sheep and mice simply cannot be extrapolated to transmission through cattle feed (a conclusion corroborated by the consensus of scientists in the field). See USDA Br. 36-37.

Finally, despite all contrary evidence, R-CALF suggests that feed bans in general are not efficacious. See R-CALF Br. 32-34. R-CALF notes that in the U.K., there were over 44,000 confirmed BSE cases in cattle even after the feed ban was implemented. See R-CALF Br. 33. The authority on which R-CALF relies (see SER 91) in fact states that there was "no doubt" that the feed ban "contributed to the decline of the disease" in the U.K., but that at first "it was not completely effective due to cross contamination between ruminant and non-ruminant feed." As noted above, Canada does protect against cross-contamination of feed. Compare also SER 25 (cited in R-CALF Br. 33) (feed bans have limited effectiveness if not enforced or unaccompanied by removal of SRMs), with USDA Br. at 27 (Canada's compliance with its food ban); infra at 19-20 (removal of SRMs); USDA Br. 39-40 (same).

R-CALF's claims that Canada does not conduct sufficient testing for BSE are similarly inaccurate. R-CALF Br. 31. Canada's testing far exceeds the levels recommended by OIE. See 70 Fed. Reg. at 468-469. R-CALF suggests that the USDA thought "'more surveillance should be required,'" R-CALF Br. 31. But the quoted passage (see SER 79) is actually a comment on the final rule submitted to USDA from "a veterinarian and rancher." SER

74. That comment obviously is not the view of the agency, which clearly rejected the comment because Canada's surveillance levels far exceed OIE recommendations.[3]

R-CALF also challenges USDA's determination that it would not require mandatory BSE testing. See R-CALF Br. 46-47. But as USDA explained, mandatory testing is worse than useless because it would produce as many as 92% false negative results. See USDA Br. 42-43.

### 3. Plaintiff Casts No Doubt On The Validity Of the Secretary's Determinations Regarding Risk Of "Dissemination" As Well As The Risk Of "Introduction" Of BSE.

The Secretary considered both the minimal risk that BSE would be introduced into the United States by Canadian cattle under 30 months of age as well as the measures that would ensure against dissemination if BSE were, in fact, introduced.

Although R-CALF suggests that the Secretary either failed to focus on the issue of "introduction" or failed to document his judgments, that is plainly not the case. See R-CALF Br. 16-21. The extensive analysis of the Canadian regulatory regime, the identified instances of BSE in Canadian cattle, and the restriction of imports to cattle under 30 months of age all addressed the obviation of risk of introduction of BSE in the

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[3] The commenter was an APHIS employee and member of the APHIS TSE Working Group, but his comments obviously are not the views of the agency. See Serono Laboratories v. Shalala, 158 F.3d 1313, 1320-21 (D.C. Cir. 1998) (subordinate employee does not speak for an agency).

first instance. See, e.g., 70 Fed. Reg. at 485-486 ("[T]he conditions specified in this rule . . . will be effective and will protect against the introduction of BSE into the United States.") (emphasis added); id. at 516 ("Based on our risk analysis, we consider these restrictions appropriate at this time to protect the United States from the introduction of BSE from minimal-risk regions such as Canada.") (emphasis added).

R-CALF is on no firmer ground when it argues that USDA erred in relying on the Harvard-Tuskegee Study which, according to R-CALF, acknowledged the inability to calculate the probability that BSE would be introduced. See R-CALF Br. 17, 25, 29. R-CALF misunderstands the purpose and function of the Study. As the Secretary explained, USDA "conducted a separate analysis to determine the risk of BSE being introduced into the United States through live ruminants or ruminant products or byproducts imported from Canada, and concluded that it is unlikely that infectious levels of BSE would be introduced into the United States from Canada under the proposed rule." 70 Fed. Reg. at 506 (emphasis added). Having concluded that there was only a minimal risk that BSE would be introduced, USDA then drew on the Harvard-Tuskegee Study, which concluded that "even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial ruminant feed and thereby infect U.S. cattle, or to result in human exposure to the BSE agent." Ibid. (emphasis added). Thus, USDA independently studied whether BSE

would be introduced from Canada, and then relied on the Harvard-Tuskegee Study to examine whether the disease (if introduced) would be disseminated. That the agency relied on the study for this purpose is unsurprising, given that its authors "did not address the likelihood of the introduction of BSE infectivity into the United States," 70 Fed. Reg. at 513, but chose instead "to posit a hypothetical introduction of five BSE-positive bulls" and then gauge the probable results, ibid. (emphasis added).[4]

R-CALF argues that the portion of the final rule requiring the removal of all special risk materials, or SRMs, from slaughtered cattle is ineffective. As discussed in our opening brief, SRMs are tissues that have demonstrated the highest levels of infectivity. USDA Br. 39-40. R-CALF raises several insubstantial objections to the requirement of SRM removal, asserting, for example, that according to an "international panel convened by the Secretary," the definition of SRMs should have included more materials than it did. R-CALF Br. 26 & n.12. The portion of the panel's statement cited by R-CALF actually stated that "[u]nless aggressive surveillance" for BSE "according to OIE

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[4] R-CALF erroneously contends that the Harvard-Tuskegee Study "acknowledg[ed] its inability to calculate a probability of introduction of BSE" because the evidence does not exist. R-CALF Br. 25. The cited evidence (SER 317) states only that the authors of the Study did not have the evidence on which to make such a calculation (not that the evidence did not or could not exist). The authors' comment is unsurprising, given that the Study was premised on the assumption that BSE would be introduced.

standards" is undertaken, then additional parts should be removed. SER 112 (emphasis added). As noted above, however, both the United States and Canada do conduct aggressive surveillance for BSE that far exceeds OIE standards.

R-CALF further argues that although SRMs "carry the highest level of infectivity in cattle," that fact is not known for an absolute certainty. R-CALF Br. 41. The USDA, however, is entitled to rely on its own best scientific judgment as to what measures present a minimal risk, and it is certainly not arbitrary or capricious to acknowledge that nothing in science is known to an absolute certainty and yet an agency must act according to the best knowledge available to it.

Finally, R-CALF points out that the final rule would permit cattle tongue to be used as food. See R-CALF Br. 41 n.19. As USDA has explained, this is because the tongue "is a muscle" and, to date, "BSE infectivity has not been detected in muscle meat of cattle." 70 Fed. Reg. at 498. R-CALF claims (see R-CALF Br. 41 n.19) that USDA had contrary evidence before it, see AR 1650. The cited study related not to cattle tongue, but to hamster tongues, and more important, the agency is entitled to rely on its own scientific assessments rather than the kind of outside studies cited by R-CALF.

### 4. Plaintiff's Discussion Of Permits For Importation Of Beef Products Is Irrelevant To This Litigation.

R-CALF contends that USDA acted arbitrarily in granting permits to import certain beef products from Canada. See R-CALF Br. 2, 11-12. The argument, even if correct, is irrelevant to the final rule enjoined by the district court. The permit system to which R-CALF refers is a different agency action than the final rule at issue here, and was the subject of litigation by R-CALF that has already been concluded in the district court. See ER 110-112 (Op. 3-5). Nor did this agency action form part of the district court's reasoning in this case. Accordingly, the existence of that permit system, its implementation by USDA, the USDA's Office of Inspector General audit report on the program (see R-CALF Br. 11-12), and the system's allowance of bovine liver to be imported (see R-CALF Br. 30 (citing 70 Fed. Reg. at 12,113 n.2) are all irrelevant to this appeal.

## C. The Final Rule Does Not Violate The Regulatory Flexibility Act.

As R-CALF concedes, the Regulatory Flexibility Act "does not mandate specific substantive measures," but merely requires the agency to consider alternatives to its rule. R-CALF Br. at 48; see also USDA Br. 43-44. As explained in our opening brief, the agency did explicitly consider (but reject) the two alternatives discussed by R-CALF, namely, country-of-origin labeling and voluntary BSE testing. See USDA Br. 44-45; 70 Fed. Reg. at 533-

34.

R-CALF argues that the agency did not consider these alternatives at all, see R-CALF Br. 50, 52, even as it concedes that they were, in fact, considered, see R-CALF Br. 51, 52 n.26. The Secretary declared in the preamble that he had considered the labeling alternative, noting that some commenters had recommended that country-of-origin labeling be required but that the agency "does not consider it necessary to delay implementation of this rule until those labeling provisions are implemented." 70 Fed. Reg. at 533. USDA also explicitly considered voluntary testing: "APHIS has considered carefully the possibility of allowing private companies to conduct their own BSE testing." 70 Fed. Reg. at 534.[5]

USDA rejected the country-of-origin labeling alternative in part because it had already been mandated by statute and because Congress expressly delayed its effective date until 2006. See USDA Br. 44-45. Although plaintiff argues that USDA was not legally compelled to reject a labeling alternative, it was plainly not required to accept it.

USDA also rejected the labeling requirement in part because it is "not a food safety or animal health measure." 70 Fed. Reg.

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[5] R-CALF apparently suggests that USDA's consideration of the voluntary testing alternative is deficient under the Regulatory Flexibility Act because it was not explicitly labeled as a "small business" consideration. R-CALF cites no authority whatsoever for that proposition.

at 533; USDA Br. 45. Even if R-CALF is correct that labeling might give consumers "additional information" for purchasing decisions, R-CALF Br. 51, a label, by itself, does not actually prevent the "introduction" or the "dissemination" of any livestock disease. Cf. Allied Local & Regional Manufacturers Caucus v. EPA, 215 F.3d 61, 80 (D.C. Cir. 2000) (where EPA rule under Clean Air Act imposed limits on volatile organic compounds in consumer products, agency acted reasonably under RFA in rejecting alternative that it "impos[e] a requirement that labels contain directions for responsible use of [those] products" because there is "no reason to believe that such an approach would accomplish the objectives of the Clean Air Act"), cert. denied, 532 U.S. 1018 (2001).

Finally, R-CALF argues that USDA's rejection of the voluntary testing alternative is illogical. See R-CALF Br. 52 n.26. But as noted, USDA rejected widespread BSE testing because it produces an overwhelming number of false negative results (as much as 92%). It is entirely reasonable for an agency to reject a test that produces such a large proportion of erroneous results. That is especially so where (as here) the vast number of erroneous results will likely undermine consumer confidence while providing no clear indication as to which if any cows are infected.

**D. The Final Rule Does Not Violate NEPA.**

1. As explained in our opening brief, R-CALF's alleged economic harms fall outside the zone of interests that NEPA is intended to address, and, in any event, alleged environmental harms would fall outside the scope of R-CALF's associational interests.

R-CALF mistakenly contends that Bennett v. Spear, 520 U.S. 154, 162-63 (1997), "restricted broad applications of the zone of interests test." R-CALF Br. 54. As the Court in that case made clear, "Congress legislates against the background of our prudential standing doctrine, which applies unless it is expressly negated." Id. at 163. The Court held that the citizen-suit provision of the Endangered Species Act expressly negated the "zone of interests" test by authorizing "any person" to commence a civil suit for violation of the Act. Congress included no similar authorization in NEPA.

R-CALF contends that it alleged sufficient environmental harm in its complaint to establish standing. R-CALF Br. 54. The complaint's sole paragraph addressing standing states that "[a]s a result of USDA's action . . . the market for R-CALF USA members' cattle will be adversely affected by" six different alleged impacts of the final rule. ER 3 (Compl. at 3 ¶ 2 (emphasis added)). It further alleges that "the Final Rule will have dramatic economic effects on U.S. cattle producers." Ibid. (emphasis added). The only mention of non-economic harm is the

assertion that its members will be harmed because they will face an "increased risk of disease." Ibid.

R-CALF does not dispute that it is a purely economic organization whose exclusive purpose is to protect its members' economic interests. It therefore does not have the requisite "associational standing" to assert purported environmental harms suffered by its members. See Hunt v. Washington State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977); USDA Br. 48.

2. R-CALF offers only one basis for its assertion that it is likely to succeed on the merits of its NEPA claim, arguing that the Secretary should have considered the impact of alleged increases in truck traffic and feedlot confinement in its Environmental Assessments (EA), an issue that no one, including R-CALF, raised during the comment process. See R-CALF Br. at 55-56 & n.29 (citing Public Citizen v. Department of Transp., 316 F.3d 1002, 1021 (9th Cir. 2003), rev'd, Department of Transp. v. Public Citizen, 541 U.S. 752, 124 S. Ct. 2204 (2004)). A litigant cannot properly challenge an agency decision on the basis of concerns it declined to raise during the comment period. Public Citizen, 124 S. Ct. at 2214.

R-CALF claims that the Supreme Court's ruling in Public Citizen is irrelevant here because in that case trucks from Mexico were required by law to be allowed over the border (so NEPA obligations could not attach), whereas letting Canadian cattle across the border is not required (so NEPA obligations

should attach). Putting aside whether such a distinction is even accurate, R-CALF overlooks the crucial part of the Supreme Court's decision. The Supreme Court did hold that the Department of Transportation had no obligation to analyze under NEPA that which it had no ability to control. 124 S. Ct. at 2217. But the Court also refused to entertain arguments, made for the first time in court, that DOT had failed to consider alternatives to its safety rules which would have had a lesser environmental impact. Id. at 2213-14. The Supreme Court found those arguments to be clearly barred by the failure to raise them at the comment stage before the agency. See ibid. (citing Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 553 (1978)).

It is that part of the Supreme Court's holding that bars R-CALF's argument here. R-CALF never asked the agency to consider truck traffic and feedlot confinement during its own NEPA commenting opportunities. Even though R-CALF asserts that "the need for an environmental impact statement in fact was discussed in comments on the proposed rule," R-CALF Br. 55 n.28 (emphasis added), the document that R-CALF cites makes no mention of alleged impacts from additional truck traffic or feedlot confinement. SER 118 (AR005065).[6]

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[6] R-CALF argues that USDA should have pointed out in its preliminary injunction opposition that R-CALF had waived its objections, R-CALF Br. 55 n.28, but this Court may address issues not raised in the district court when, as here, "the issue

In any event, as demonstrated in our opening brief, the agency fully considered the environmental impacts of the Final Rule issued on January 4, 2005, and provided the public more than 100 days to comment on the potential environmental impacts of the Final Rule. USDA Br. 49-51. USDA's subsequent issuance of its Finding of No Significant Impact and Affirmation of the Final Rule on April 8, 2005, renders R-CALF's objections to the Final Environmental Assessment moot, since the FONSI addressed the environmental consequences of increased trucking and feedlot confinement. 70 Fed. Reg. at 18,260-62. See Safari Aviation v. Garvey, 300 F.3d 1144, 1150 (9th Cir. 2002); ALCOA v. Bonneville Power Admin., 175 F.3d 1156, 1163 (9th Cir. 1999).

## II. THE BALANCE OF HARMS DOES NOT SUPPORT A PRELIMINARY INJUNCTION.

As explained above, R-CALF has failed to demonstrate even a serious question on the merits, let alone a likelihood of success. The balance of harms also does not support the entry of a preliminary injunction.

R-CALF has acknowledged in a related appeal that the USDA's rule does not jeopardize human health. Despite oblique suggestions to the contrary here, see R-CALF Br. 5, 10, 19, 57 n.31, R-CALF explicitly stated in its brief in that appeal that it has "never argued that there was a great risk to human health

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presented is purely one of law," and "the pertinent record has been fully developed." Bolker v. Commissioner of Internal Revenue, 760 F.2d 1039, 1042 (9th Cir. 1985).

from resumed imports of cattle and beef from Canada." R-CALF Br. in No. 05-35214, at 44. R-CALF could not seriously advance such an argument, given the careful scientific scrutiny USDA gave to the overlapping and complementary safeguards for human and cattle health that are employed by its final rule, see USDA Br. 8-12, 20-29, and the absence of even a single probable or confirmed case of human infection from consuming Canadian beef, see USDA Br. at 58.

There also is no serious argument that the final rule would cause the spread of BSE among domestic cattle should an infected animal enter the United States. BSE is not a contagious disease and is not spread through cattle-to-cattle (or cattle-to-human) contact. Rather, the only scientifically documented route of BSE infection for cattle is by eating contaminated cattle feed, see 70 Fed. Reg. 460, 486 (Jan. 4, 2005), and the United States has its own effective feed ban, see id. at 466. Indeed, R-CALF itself is using the district court's preliminary injunction to profit from the sale of the very same Canadian cattle it contends are unsafe for importation. See USDA Br. at 58-59.[7]

R-CALF's assertion that the balance of harms requires an

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[7] R-CALF does not dispute that its members have purchased the same beef that it characterizes as unsafe. It obliquely suggests, however, that the Court should ignore its actions because they post-date the preliminary injunction hearing. R-CALF Br. 16 (citing USDA Br. at 59). We do not rely on R-CALF's conduct. Nevertheless, it is a matter of public record and need not be ignored.

injunction rests entirely on its claim of economic harm. R-CALF urges, in other words, that the Secretary's considered safety determination should be set aside to protect R-CALF from speculative loss of profits. In so doing, R-CALF asks the Court to ignore the real and present harm resulting from the injunction each day to other segments of the economy as well as to our trading partners. Gains by one part of the beef industry (such as R-CALF) can be expected to result in corresponding losses for other segments of the same industry, see USDA Br. 59, and gains to cattle producers are in relative equipoise with losses to consumers, see 70 Fed. Reg. at 542.[8]

In short, R-CALF has managed to secure an unwarranted economic advantage for several months based on speculative threats to its future economic interests. This state of affairs should not be permitted to continue, and we ask that the injunction be vacated at the earliest possible time.

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[8] R-CALF erroneously states that USDA's estimate of the economic benefits of the rule is only $11 million. See R-CALF Br. 27. In fact, the cited reference is to R-CALF's own argument before the district court. See SER 254. USDA's actual estimates are in the hundreds of millions, if not billions, of dollars. See ER 90 (Fillo Decl. ¶ 8); 70 Fed. Reg. at 518.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and the preliminary injunction vacated.

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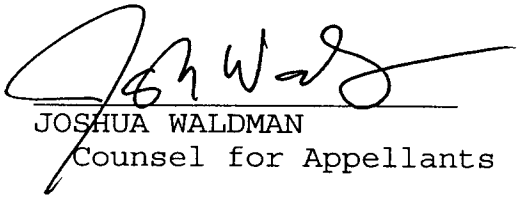
JUNE 2005

**CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)(B) AND NINTH CIRCUIT RULE 32-1**

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and (C) and Ninth Circuit Rule 32-1, I certify that the attached Reply Brief for Appellants is monospaced, has 10.5 or fewer characters per inch and contains no more than 6,989 words.



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**CERTIFICATE OF SERVICE**

I hereby certify that pursuant to Fed. R. App. P. 25(d)(2) and 31(b) and Ninth Circuit Rule 30-1.2, on June 9, 2005, I caused two copies of the foregoing Reply Brief for Appellants to be served by Federal Express overnight delivery on the following:

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